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EXAMINER	
FLORY, CHRISTOPHER A	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,985	YANAGA, AKIHIKO	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5 and 11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 4, 5 and 11-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

2. Claim 11 is objected to because of the following informalities: Claim 11 is listed as depending from cancelled claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not recite that the arm portions of the device are rigidly attached to the body case, nor is this feature made obvious from the drawings.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 stands, and claims 12 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Granzotto et al. (US Patent 6,757,392, hereinafter Granzotto'392) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto'392, or Granzotto'392 in view of Reinhold, Jr. (US Patent 5,339,823, hereinafter referred to as Reinhold'823), or Granzotto'392 in view of Marangoni (US 4,535,783, hereinafter Marangoni'783).

Regarding claim 1, Granzotto'392 discloses an electrocardiograph (column 1, lines 60-67) comprising a body case (Fig. 1, headpiece 1) which is held on a chest portion of a subject (ABSTRACT; column 3, lines 8-22); a common electrode provided on a back surface of said body case (Fig. 4, fixed electrode 16); a pair of arm portions which extend from said body case (Fig. 4, arms 18); electrodes for detecting electrocardiographic complex which are provided in both end portions of said pair of said arm portions respectively (Fig. 4, electrodes 17; column 2, lines 1-7); a detecting means for detecting electrocardiographic complex based on signals detected by said electrodes (column 4, lines 51-59); a display means for displaying said electrocardiographic means (Fig. 3, LCD 11 displays the electrocardiographic complex

and heart rate); a transmitting means for transmitting said electrocardiographic complex (LCD 11 can be considered a transmitting means; likewise, circuitry or wiring between the disclosed memory and display constitutes a transmitting means. Granzotto'392 shows said body case suspended from a neck of said subject by a suspending means (Fig. 1, flexible bows 31; column 2, lines 3-39).

Further regarding the switching means of claim 1, Granzotto'392 discloses switching contacts at pivot joints 19 for the purpose of connecting electrodes 17 to the main body electrode only when the arms are in a fully extended position (column 4, lines 7-27), while the unit will otherwise function as a passive ausculatory device. This can clearly be seen as a disclosure of a switching means that would start detection, display and transmission of the electrocadriographic complex to the LCD, where data would only be recorded if the device were placed in contact with the chest portion of the subject. Granzotto'392 further discloses that the arm parts are molded of a flexible plastic and incline at an obtuse angle which changes under pressure on the stethoscope head, and further that such manual pressure on the stethoscope head is necessary to achieve firm contact of the electrodes to detect, display and record the electrocardiographic information (column 4, lines 1-47, emphasis on lines 28-47). This can reasonably be considered a disclosure of push-down switches either in that the arm pivot switching contacts or the electrodes themselves must be pushed down with this manual pressure in order to make contact with all electrodes to the skin in order to detect, display and record the electrocardiographic complex, such that when this push-

down pressure is not applied, contact is not made and the ECG complex is not detected.

Alternatively, push-down switches located in the electrode contacts of externally applied ECG and heart rate acquiring electrode devices are well-known in the art (e.g. treadmills, bathroom scales, or other devices where bi-point electrocardiographic data acquisition is desired through a gripping or weight-bearing means) as a simple to manufacture and reliable means of conserving battery or device power by disconnecting the ECG circuit when the user is not applying gripping or weight-bearing pressure on the device since no useful data could be collected in such a situation. Simultaneous application of pressure to both electrode contacts in these configurations initiates ECG collection, analysis and readout. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Granzotto'392 with push-down switches located in the electrodes to provide Granzotto'392 with the same well-known advantages of conserving device power by only collecting ECG data when pressure is applied to the electrodes to signify a significant connection to a patient for whom collection of ECG data is desired.

Still further in the alternative, Reinhold'823 teaches a device wherein human pressure is applied to engage an array of electrodes with the skin of the chest of an individual to place the electrodes in an operative relation to obtain electrocardiogram data from the individual (abstract; column 2, lines 20-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392 with the pressure-activated electrodes and control protocol as

taught by Reinhold'823 to provide Granzotto'329 with the same advantage of engaging an electrode array to the chest in an operative relation so as to be able to effectively obtain electrocardiogram data.

Still further in the alternative, Marangoni'783 teaches an electrocardiography recorder in which electrodes (Fig. 1A, electrodes 7 and 8) are disposed over an pressure switch (Fig. 4, switch 21) in such a way that the switch is actuated when the contacts are brought into contact with the skin with a predetermined minimum satisfactory pressure to initiate recording of ECG data, and not record ECG data otherwise (column 4, lines 19-38). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Granzotto'392 with the press-down electrode switching means as taught by Marangoni'783 to provide Granzotto'392 with the same advantage of recording ECG data only when satisfactory pressure contact between the electrodes and the skin have been made.

Regarding the limitation that the body case and pair of arm portions form a T-shape, it is noted that Figure 5 of Granzotto'392 clearly shows a t-shaped device with the top arms forming the crossbar and the bottom arm and body forming the vertical base. Alternatively, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Granzotto'392 with the t-shaped configuration, because Applicant has not disclosed that said t-shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the configuration as taught by Granzotto'392,

because it provides a means for properly positioning the recording electrodes and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Granzotto'392 .

Regarding the limitation that the T-shape be inverted when suspended from the neck, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the body case 1 of Granzotto'392 is clearly capable of being held in an inverted orientation from the flexible suspension means 4 (see Fig. 1).

Regarding claim 12, arm joints (19) of Granzotto'392 can reasonably be considered rigidly fixed using several definitions of the word rigid, such as unyielding, firm, exacting, thorough, rigorous or "so as to meet precise standards." Although the joints are rotational, they are constructed in a solid, or unyielding and firm, manner so that the device may be used consistently, repeatedly and accurately over time. Further, the device would be constructed using exacting and thorough standards of construction in order to meet precise design standards. Alternatively, Reinhold'823 clearly shows a device with rigidly attached arm portions (Fig. 5, where arm portions are considered to contain electrodes V1, V2, V5 and V6) in order to conform to the body and maintain proper electrode alignment under pressure.

Regarding claim 13, Granzotto'392 can reasonably be interpreted as elongated and clearly shows a first and second ends where the arm portions are attached. Alternatively, Reinhold'823 is clearly elongated.

7. Claims 4, 5 and 11 stand rejected under 35 U.S.C. 102(b) as anticipated by Granzotto'392 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto'392 in view of Reinhold'823, or still alternatively as obvious over Granzotto'392 in view of Marangioni'783 further in view of Reinhold'823.

Regarding claims 4 and 5, it is evident from the scope of the disclosure in Granzotto'392 that non-paste electrodes are inherently necessary for proper function of the Granzotto'392 device. It is well known that stethoscopes operate by being placed temporarily on the chest of a subject and are held there by human force rather than adhesive means. Granzotto'392 further discloses that electrodes 17 are moveable (column 4, lines 1-27) and applied through pressure (column 4, lines 45-47) rather than adhesive means.

Alternatively in the same field of endeavor, Reinhold'823 teaches the use of non-adhesive precordial electrodes on an electrocardiograph device in which human pressure is applied to engage the array of six precordial electrodes with the skin of the chest of the individual in an operative relation (ABSTRACT; column 4, lines 54-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392 with the non-adhesive electrodes of Reinhold'823 to provide the Granzotto'392 system with the advantage of temporarily

applying the device to a patient in an operative relation with human pressure contact (motivation to combine provided by Reinhold'823 ABSTRACT; column 4, lines 54-66).

Regarding claim 11, the suspending means of Granzotto et al. is considered to be detachable because the bows 31 are made of a rigidly flexible material known in the art which hold the device on the neck of a user while in their resting configuration, but can be manually separated to allow removal of the device from the neck. The suspending means of Granzotto et al. is detachable to said body case because the bows 31 could be physically removed from the chest-piece 2 without altering in any way the function of the electrocardiograph subsystem.

Alternatively in the same field of endeavor, Reinhold'823 teaches an electrocardiograph device employing a lanyard for engagement around the neck of the user (column 5, lines 1-20). It is well known that a lanyard, such as one used on a set of keys or on a personal camera, comprises a separate flexible loop body (typically fabric) that is attached in a releasable manner to the main body of a device, either by tying through a hole in the device body, attaching to the device body by a key ring, or releasably inserting a male connector portion into a compatible female connector portion. This establishes a detachable quality to the lanyard taught by Reinhold'823. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392with the detachable lanyard as taught by Reinhold'823 to provide the Granzotto'392system with the same advantage of releasably engaging the device around a user's neck and allowing for proper vertical

adjustment of the electrodes to record an electrocardiographic complex (motivation to combine provided by Reinhold'823, column 5, lines 1-20).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

28 June 2008

/George Manuel/
Primary Examiner